

Attorney Docket No.: DEX-0205  
Inventors: Pluta et al.  
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consisting of claims 1-6 and 9, has been examined. Accordingly, Applicants have canceled claims 7-8 and 10-25 without prejudice. Claims 1-6 and 9 have been rejected. Claims 1 have been amended. Claim 2 has also been canceled. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### **I. Finality of Restriction Requirement**

The Examiner has made final the Restriction Requirement mailed November 27, 2001 and clarified that elected Group I consists of claims 1-6 and 9. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled claims 7-8 and 10-25, without prejudice. However, in light of the finality of this Restriction Requirement, Applicants reserve the right to file divisional applications to the canceled subject matter.

#### **II. Rejection of Claims under 35 U.S.C. § 112, first paragraph**

Claims 1-6 and 9 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner has acknowledged the specification to be enabling for an isolated polynucleotide comprising SEQ ID

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NO:2. However, the Examiner suggests that the specification does not reasonably provide enablement for a polynucleotide fragment of SEQ ID NO:2 wherein the fragment is at least 15 contiguous nucleobases long. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to delete part (b) relating to polynucleotide fragments.

With respect to claims 1-2, the Examiner also suggests that it would require undue experimentation for one skilled in the art to practice the invention as claimed with respect to a polynucleotide which comprises variations or which hybridizes to an antisense sequence of SEQ ID NO: 2, or an antisense oligonucleotide which hybridizes to a polynucleotide of claim 1. Specifically, the Examiner suggests that applicant has not taught how to hybridize identical nucleic acid strands or, for example, a degenerate strand of SEQ ID NO:2 to that of SEQ ID NO:2, one to the other. The Examiner also suggests that the specification does not disclose whether the polynucleotide sequences hybridize partially or completely or which regions of the strands are hybridizing. Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that claim 1 is not drawn to hybridizing identical nucleic acid strands or hybridization of a degenerate strand of SEQ ID NO:2 to that of

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SEQ ID NO: 2. Instead, the claims are drawn to a nucleic acid sequence which hybridizes under stringent conditions to **an antisense sequence** of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13.

Applicants also respectfully disagree with the Examiner's suggestion that the specification does not disclose the type of hybridization required. Claim 1 specifically states that the nucleic acid hybridizes under **stringent conditions**. Further, a definition for stringent hybridization is provided in the specification at page 16, lines 27-30. This definition has been amended to clarify that for stringent hybridization the antisense sequence must have 95% or more preferably 97% identity with SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13. Support for this amendment can be found in claim 1 as originally filed and in the specification at page 3, lines 6-12, page 3, line 33 through page 4, line 2, page 16, lines 24-27 and page 33, lines 10-16. Thus, no new matter is added by this amendment.

The identification of a nucleic acid sequence which has at least 95% identify with SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13 so that it hybridizes under stringent conditions to an antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9,

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10, 11, 12 or 13 can be performed routinely by one of skill in the art in accordance with well known techniques. Thus, contrary to the Examiner's suggestion, it would not require undue experimentation to practice the invention as claimed.

In an earnest effort to advance the prosecution of this case, however, Applicants have canceled claim 2 and amended claim 1 to delete reference to variant sequences.

Withdrawal of these rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested in light of the amendments to the specification and claims and the above arguments.

### III. Rejection of Claims under 35 U.S.C. § 102(b)

Claims 1-6 and 9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Kato et al. (1983). The Examiner suggests that Kato et al. discloses a genomic clone that contains the human gastrin gene which may partially hybridize to a fragment, variation and antisense sequence of SEQ ID NO:2 and therefore anticipates claim 1. Further, with respect to claim 9, the Examiner suggests that it is inherent that the polynucleotide may be used to diagnose stomach cancer since it was derived from the gastrin gene.

Applicants respectfully traverse this rejection.

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The gastrin gene taught by Kato et al. is a polynucleotide sequence with only 92% similarity over only a portion of SEQ ID NO:2. As discussed in detail in Section II, *supra*, claim 1 has been amended to remove any reference to fragments or variants. Further, as also discussed in Section II, *supra*, a nucleic acid sequence which hybridizes under stringent conditions to an antisense sequence of SEQ ID NO: 2, in accordance with the definition in the specification must have at least 95% identity with SEQ ID NO:2. Accordingly, since Kato et al. does not teach a nucleic acid sequence with all of the elements of the present invention, this reference cannot anticipate the claims as amended. It is therefore respectfully requested that this rejection be withdrawn.

#### IV. Conclusion

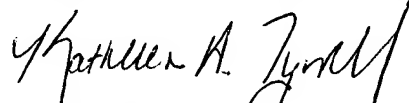
Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The

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attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES  
MADE."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Please replace the paragraph extending from page 16, line 13, through page 17, line 3, as follows:

For purposes of the present invention, by polynucleotides it is meant to include isolated nucleic acid sequences comprising single- and double-stranded DNA, DNA that is a mixture of single- and double-stranded regions, single and double-stranded RNA or hybrids thereof wherein the sequences comprise SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13, fragments of at least 15 contiguous nucleobases of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13, nucleic acid sequences which, due to degeneracy in genetic coding, comprise variations in polynucleotide sequence as compared to SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13, but which still encode the same protein, and nucleic acid sequences which are capable of hybridizing under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13. By stringent conditions it is meant that hybridization with the antisense sequence will occur only if there is at least 95%, and more preferably at least 97% identity ~~between the sequences~~ with SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13. RNA sequences may be in the form of

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mRNA while DNA sequences may be in the form of cDNA or genomic DNA obtained by cloning or produced by chemical synthetic techniques or by a combination thereof. As used herein, the term polynucleotide also includes DNAs or RNAs, as described above, that contain one or more modified bases. Examples of modified bases include, but are not limited to, backbone modifications to increase stability and incorporation of unusual bases such as inosine or tritylated bases.

**In the Claims:**

Please cancel claims 2, 7-8 and 10-25 without prejudice.

Please amend the claims as follows:

1. (amended) An isolated polynucleotide comprising:

(a) SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13;

~~(b) a fragment of at least 15 contiguous nucleobases of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13;~~

~~(c) a nucleic acid sequence which, due to degeneracy in genetic coding, comprises variations in nucleotide sequence as compared to SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13, but which still encodes the same protein; or~~

~~(d)~~ (b) a nucleic acid sequence which hybridizes under stringent conditions to an antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13.